Supreme Court, U.S.
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No. 92-___

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

JENNIFER STAMPS,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, that bars states from "establishing or continuing in effect" device requirements that are "different from, or in addition to" a requirement under the MDA, preempts all state-law damage claims against a manufacturer of a medical device approved for marketing by the Food and Drug Administration ("FDA") where:

> (1) there are no specific federal regulatory requirements for the device in question that coincide with petitioner's state law claims, and (2) the FDA's own view is that the MDA does not preempt damage claims.

PARTIES TO THE PROCEEDINGS

In addition to petitioner Jennifer Stamps and respondent Collagen Corporation, who appeared as appellant and appellee, respectively, in the court of appeals, the State of Texas, the Association of Trial Lawyers of America, the Health Industry Manufacturers Association, and the Product Liability Advisory Counsel, Inc. appeared as *amici curiae* in the court of appeals.

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JENNIFER STAMPS,
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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Fifth Circuit is reported at 984 F.2d 1416 (1993), and is reproduced in the appendix at 1a-15a. The unreported decision of the United States District Court for the Southern District of Texas is reproduced in the appendix at 16a-18a.

JURISDICTION

The judgment of the court of appeals was entered on February 19, 1993. Petitioner filed a timely petition for rehearing on March 5, 1993, which was denied by the court of appeals on March 19, 1993 (19a). This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to

a device intended for human use any requirement--

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

> **(1)** the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> **(2)** the requirement--
>
> > **(A)** is required by compelling local conditions, and
> >
> > **(B)** compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only

> when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT

This case presents the question of whether, under the Medical Device Amendments ("MDA") to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the Food and Drug Administration's decision to allow the marketing of a medical device insulates the manufacturer from all state-law damages liability. In 1988, petitioner Jennifer Stamps was administered respondent's medical devices, known as Zyderm and Zyplast, which were injected under petitioner's skin to remove skin deformities (2a-3a). Shortly after the injection, petitioner began to suffer from dermatomyositis/polymyositis ("DM/PM"), an autoimmune disease "in which an individual's immune system identifies one's own skin and muscle tissue as foreign and attacks them" (3a). Specifically, petitioner alleged that, within about a

month of receiving the injection, she was suffering from extreme pain and weakness in her muscle and joints, and esophageal insufficiency, causing her great difficulty in walking, among other disabling conditions. Original Petition, ¶ II.

Petitioner filed suit in Texas state court in 1990, alleging, among other things, that the medical devices were defectively designed and that respondent knew of the relationship between Zyderm and her illness but failed to warn her of that fact. *Id.* ¶¶ IV, V. She based her claims on negligent failure to warn, defective labeling, strict liability, and negligence *per se* under Texas common law (3a). Respondent removed the case to federal court based on diversity of citizenship.

Without addressing the merits, the district court and the court of appeals dismissed all of petitioner's claims on the ground that they were preempted by the MDA (15a, 18a). *See* 21 U.S.C. § 360k(a). This case presents the same legal questions as are before this Court in *King v. The Collagen Corporation*, No. 92-1979, filed on June 13, 1993, which was decided by the First Circuit about a month before the decision below.[1] Indeed, as the court of appeals below noted, the two cases concern the same manufacturer and medical device (7a), and counsel for both petitioners and respondent are the same in both cases.

Given the identity of the two cases, petitioner Stamps does not reiterate in full the arguments set forth in the petition in *King*, but asks only that this Court dispose of this petition in a manner consistent with *King*. Thus, if the Court grants certiorari in *King*, as we believe it should, the Court should either hold in abeyance this petition pending the disposition in *King*, or grant certiorari here and consolidate the two cases for plenary review. If certiorari is denied in *King*, then it should be denied here as well.

However, as fully described in the *King* petition, certiorari should not be denied because the issues presented here are of great importance to the medical-device industry, medical-device consumers, and to the Food and Drug Administration ("FDA"), whose regulations and other rulings counsel strongly against the

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[1] *King* was decided by the First Circuit on January 15, 1993, with rehearing denied on February 3, 1993, while the decision below was rendered by the Fifth Circuit on February 19, 1993, with rehearing denied on March 19, 1993.

decision here and in *King*.[2] As noted in the *King* petition, the FDA's former Chief Counsel has called that case "probably the single most important case to the medical-device industry in American history."[3] The fact that injured consumers living in the geographical area of two courts of appeals are now without any remedy against manufacturers of the most potentially injurious medical devices only reinforces the need for review by this Court.

CONCLUSION

The petition for a writ of certiorari should be disposed of in a manner consistent with the Court's disposition of the petition in *King v. The Collagen Corporation*, No. 92-1979 (filed June 13, 1993).

Respectfully submitted,

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[2] *See King* Petition at 14-15, 21-22, 24 & n.17.

[3] Edward Felsenthal & Lee Berton, *FDA Approval Shields Firms in Injury Suits*, Wall St. J., Jan. 21, 1993, at B1 (quoting Peter Hutt, former FDA Chief Counsel).

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

[FILED FEB 19, 1993]

No. 92-2084

JENNIFER STAMPS,

Plaintiff-Appellant,

VERSUS

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

Before GOLDBERG, SMITH, and EMILIO M. GARZA, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

Contending that she contracted a rare autoimmune disease from being injected with defendant Collagen Corporation's ("Collagen") products, Jennifer Stamps filed suit to recover damages in state court, alleging causes of action based upon defective design, inadequate warnings, and negligent failure to warn. Collagen timely removed and thereafter moved for summary judgment. The district court found all of Stamps's state law claims to be preempted by federal law and granted summary judgment. We affirm.

I.

A.

Zyderm and Zyplast are so-called Class III medical devices regulated under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360l, pursuant to which the Food and Drug Administration ("FDA") classifies all medical devices in one of three categories. See 21 U.S.C. § 360c. Class I devices generally pose little or no threat to public health and safety; tongue depressors are an example. Accordingly, Class I devices are subject only to general controls on manufacturing processes.

Class II items are more complex than Class I and include such devices as oxygen masks used in anesthesiology and tampons. These may be subject to recommendations, guidelines, post-marketing surveillance, the development of patient registries, and even the promulgation of specific performance standards, should the FDA deem them a sufficient health hazard as to require strict product specifications or warnings. See 21 U.S.C. § 360c(a)(B).

Class III devices, such as Zyderm, require premarket approval ("PMA"), which process permits the FDA to determine whether a proposed product provides "reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(C). Such devices are subject to the more stringent PMA process because they "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

The PMA process requires a manufacturer to submit a detailed application to the FDA, including information pertaining to product specifications, intended use, manufacturing methods, and proposed labeling. See 21 U.S.C. § 360e(c). The FDA refers each application to a panel of qualified experts that prepares a report and recommendation. Within six months, the FDA must either accept or reject the application. 21 U.S.C. § 360e(d).

B.

In March and April 1988, Stamps was injected with Zyderm and Zyplast, which contain processed bovine collagen that Collagen markets as an anti-wrinkle treatment for middle-aged women. A typical treatment consists of a series of injections

directly under the skin, the collagen then remaining to smooth out any wrinkles or deformities on the skin's surface.

Shortly after receiving her injections, Stamps began complaining of muscle and joint pains that subsequently were diagnosed as dermatomyositis/polymyositis ("DM/PM"). DM/PM is a relatively rare autoimmune disease in which an individual's immune system identifies one's own skin and muscle tissue as foreign and attacks them. Stamps claims that Collagen's products attached to her tissues and provoked an immune response that destroyed her body tissue.

II.

In granting summary judgment, the district court likened the instant case to Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989), in which we found a plaintiff's state-law-based failure-to-warn and labeling claims regarding a Class II medical device (tampons) to be preempted, although her defective construction and design claims survived. Reasoning that collagen implants are regulated under Class III, which requires FDA pre-market approval of not just labeling and packaging, but manufacturing methods as well, see, e.g., 21 C.F.R. §§ 814.20, 814.80, the court concluded that Stamps's claims are completely preempted.

Appellant Stamps disputes the district court's interpretation of the MDA and its application of Moore, contending that the MDA neither expressly nor impliedly preempts general state tort law and that Moore must be limited to the Class II regulatory context it describes. As a final matter, Stamps argues that even if we find Moore compelling precedent in the Class III context as well, the most it can be said to require is the preemption of her defective labeling and negligent failure-to-warn claims; her products liability, fraud, and negligence per se causes of action, as in Moore, should be reinstated.

III.

The question is whether the MDA preempts Stamps's state law claims. The Supremacy Clause of the Constitution invalidates state laws that "interfere with, or are contrary to" federal law, U.S. Const. art. VI, cl. 2. When "the field which Congress is

said to have preempted has been traditionally occupied by the States . . . 'we start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress.'" Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (citations omitted); see also Hillsborough County v. Automated Medical Lab., 471 U.S. 707, 715 (1985) (recognizing a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause"). Accordingly, "'[t]he purpose of Congress is the ultimate touchstone'" of preemption analysis. Malone v. White Motor Corp., 435 U.S. 497, 504 (1978) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)).

Congress's intention to preempt may be either express or implied from the statutory text. Absent an express declaration, Congressional intent to preempt state law may be inferred only if state law actually conflicts with federal law, see Pacific Gas & Elec. Co. v. Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983), or where the scheme of federal legislation is so comprehensive "'as to make reasonable the inference that Congress left no room for the States to supplement it.'" Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting Rice, 331 U.S. at 230).

IV.

A.

The Supreme Court's most recent and authoritative treatment of preemption doctrine is Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). In Cipollone, a plurality held that a lung cancer victim's suit against cigarette manufacturers alleging breach of warranty, failure to warn, fraudulent misrepresentation, and conspiracy to deprive the public of medical information regarding smoking was not preempted by the 1965 Federal Cigarette Labeling and Advertising Act; certain of her failure to warn and fraudulent misrepresentation claims were, however, preempted by the language added by Congress to the Public Health Cigarette Smoking Act of 1969. Id. at 2625.

In Cipollone, the Court relied exclusively upon the express language of the statutory provision regarding preemption. Reasoning that "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted," the Court concluded,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a "reliable indicium of congressional intent with respect to state authority," "there is no need to infer congressional intent to pre-empt state laws from the substantive provisions" of the legislation....Therefore, we need only identify the domain expressly pre-empted by [the statute].

112 S. Ct. at 2618 (citations omitted). See also id. at 2625 (Blackmun, J., concurring) (same).

The MDA was enacted in 1976 as an amendment to the Federal Food, Drug and Cosmetic Act of 1938. Like the Public Health Cigarette Smoking Act addressed in Cipollone, it contains a provision expressly addressing its intended preemptive scope:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (Supp. 1992).

B.

Applying Cipollone, we reject, at the outset, Collagen's contention that we may resort to the doctrine of implied preemption to uphold the district court. The existence in the MDA of an express preemption provision precludes any such reliance.

C.

We likewise must reject Stamps's argument that Congress did not intend to preempt state tort law remedies when it enacted the MDA. Section 360k(a) speaks broadly: Any state requirement "different from, or in addition to," federal law is preempted.

Moreover, Stamps's contention that the MDA does not preempt common law tort actions is necessarily foreclosed by Moore. Implicit in our holding that certain of Moore's state law claims were preempted by the applicable FDA Class II regulations is the conclusion that Congress intended the preemption of state tort liability where such liability effectively creates a requirement "different from, or in addition to" specific federal requirements. Congress, of course, has the power so to displace state tort law remedies. See, e.g., Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311, 331 (1981) (state common law may be preempted by federal law).

This result is fortified not merely by Moore's compatibility with the analysis pursued in Cipollone but also by the Court's determination that the language of the statute at issue there, preempting any state "requirement or prohibition," "sweeps broadly and suggests no distinction between positive enactments and common law...." Cipollone, 112 S. Ct. at 2620. It would be anomalous to interpret the MDA differently from the Public Health Cigarette Smoking Act solely on the basis that while they both employ "requirement," the MDA omits "prohibition."[1] Thus, Moore correctly decided this issue; section 360k(a) also "sweeps broadly" and encompasses common law tort actions within its preemptive scope. See also Morales v. Trans World Airlines, Inc., 112 S. Ct. 2031, 2037 (1992) (finding state common law actions "relating to" airline advertising preempted by Airline Deregulation Act of 1978).

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[1] Indeed, the FDA regulation that parallels § 360k(a), 21 C.F.R. § 808.1(b), extends the "any requirement" language of that section to any medical device standard "having the force and effect of law (whether established by statute, ordinance, regulation, or court decision) . . . . " (Emphasis added.)

D.

Returning to Cipollone's admonition that our inquiry be guided solely by the express language of the statute's preemption provision, we glean from section 360k(a) the following analysis: A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA.[2] See also King v. Collagen Corp., 1993 U.S. App. LEXIS 432, at *12-*13 (1st Cir. Jan. 15, 1993) (applying similar test to identical product).

By this test, we find that our decision in Moore logically extends to the FDA Class III regulatory context and that Stamps's claims may be preempted under the MDA. Simply put, Texas tort liability, following Cipollone, would constitute a requirement either different from, or in addition to, a requirement -- the Class III PMA process - that the MDA has made applicable to Zyderm and Zyplast. The second part of the analysis, involving as it does the "relates to" language of section 360k(a)(2) recently given a sweeping interpretation by the Supreme Court in Morales, 112 S. Ct. at 2037-38, is even simpler than the first. In the context of this case, Stamps's state law claims undoubtedly "relate to" either

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[2] The FDA's gloss on § 360k(a) poses essentially the same test:

> (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] of the act because they are not "requirements applicable to a device" within the meaning of section [360k(a)] of the act.

21 C.F.R. § 808.1(d). As with administrative agencies generally, the FDA's construction of the statute is entitled to "controlling weight unless it is plainly erroneous or inconsistent with the regulation." Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945). Neither party contests the validity of the FDA's regulations pursuant to the MDA.

the safety or effectiveness of Zyderm and Zyplast, or to some other matter included in the PMA requirements applicable to She products.[3]

V.

Because the MDA, like the statute at issue in Cipollone, fails to "indicate that any familiar subdivision of common law claims is or is not pre-empted," Cipollone, 112 S. Ct. at 2621, we must pursue the "straightforward" inquiry commended to us by the Supreme Court: "[W]e ask whether the legal duty that is the predicate of the common law damages action constitutes" a requirement relating to the safety or effectiveness of Zyderm and Zyplast or to any other matter included in a requirement made applicable to it by the MDA. Id.

A.

We need not conduct a categorical inquiry into each cause of action pursued by the plaintiff, as did the Court in Cipollone, as Moore tells us that Stamps's inadequate labeling (paragraph IV of the original petition) and failure to warn (paragraph V) allegations are preempted by the MDA. The Class III regulatory structure, no less than that of Class II, involves the FDA in considerable oversight regarding proposed package labeling of a device.[4] Nor can Stamps's third cause of action (paragraph VI), based upon the defective design and manufacture of Collagen's products, survive

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[3] Applying the language of § 808.1(d), see supra note 2, yields the same result: The PMA process constitutes a "specific requirement[] applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

[4] See 21 U.S.C. § 360e(c)(1)(F) (requiring PMA application to contain samples of device's proposed labeling); 21 C.F.R. § 814.20(b)(10), (e) (same); see also 21 U.S.C. § 360e(d)(2)(A) -(B),(D) (requiring denial of PMA application for insufficient showing that the device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," or if the proposed labeling is false or misleading in any particular).

preemption, as the Class III PMA process includes FDA scrutiny and approval of these particular aspects of a device.[5]

B.

Stamps's claim that even if preemption applies to the Class III context, the MDA preempts state law only to the extent that the

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[5] See 21 U.S.C. § 360e(c)(1)(B)-(C) (requiring, in PMA application, statements and descriptions of the ingredients, components, methods, controls, and facilities used in the manufacture and processing of the device); id. § 360e(d)(2)(C) (requiring denial of application where "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title..."). See also 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.").

Moreover, § 360j(f)'s "[g]ood manufacturing practice requirements" impose further requirements upon the manufacture of Class III devices, leaving us with little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture, in the form of common law products liability duties.

Lastly, we note that we have not analyzed Stamps's fraud-based cause of action in accordance with Cipollone because we are convinced that her original petition contains no adequate averment of fraud. Although the petition does state in paragraph V that "Defendant engaged in an active campaign to suppress the facts, blame the adverse reactions on some other cause, and prevent discovery of the risks associated with its products," this sentence comes sandwiched between allegations of negligence in a paragraph that concludes only that "Defendant's conduct was negligent and was the proximate cause of Plaintiff's damages." Such an allegation of fraud would not suffice under Fed. R. Civ. P. 9(b); and while Stamps is technically correct that the burden lies with the defendant to request a more definite statement under Fed. R. Civ. P. 12(e) when a pleading or allegation is too vague or ambiguous to admit of a response, we do not believe such was the case here. Paragraph V is not vague or ambiguous; it reads quite plainly as an allegation of negligence. Albeit liberal with respect to the formalities, notice pleading is yet to be distinguished from reading tea leaves. To require Collagen to move for a more definite statement in order to determine whether, when Stamps pled negligence, she in fact meant fraud, would go far towards erasing that distinction.

state mandates a similar PMA process, presents a close question. In Larsen v. Pacesetter Sys., 837 P.2d 1273, 1282 (Haw. 1992), for example, the court has found that an implant patient's claims arising from the recall of a "substantially equivalent" Class III pacemaker were not preempted by the MDA, noting that "the statutes and regulations governing premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis under [21 C.F.R.] § 808.1(b)."[6] On this subject, the FDA has stated,

> Like all other medical device requirements, different or additional State and local [PMA] requirements are preempted when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act.

43 Fed. Reg. 13,664 (1978) (emphasis added).

This passage might be construed exclusively -- to the effect that only different or additional state PMA processes are preempted when the FDA has classified a device under Class III. We believe, instead, that the emphasized language above - added to the fact that the passage was written in response to public comments seeking clarification from the FDA as to "whether or when State and local

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[6] Larsen is distinguishable from the instant case in that it involved a device that passed through a less stringent Class III review process by virtue of its being "substantially equivalent" to devices already allowed to be marketed. As the court stated, "Although a determination of substantial equivalence involves a review by FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness." Larsen, 837 P.2d at 1282 (citing H.R. Rep. No. 8081, 101st Cong., 2d Sess. 14, reprinted in 1990 U.S.C.C.A.N. 6305, 6307; 21 C.F.R. § 807.97 (FDA's acceptance of claim of substantial equivalence does not denote official approval of the device)).

The instant devices are not "substantially equivalent" to marketable devices rather, they have been subjected to the full rigor of the PMA process. While we do not rely upon this ground, one could argue that 21 C.F.R. § 807.97's explicit statement that the FDA does not officially approve "substantially equivalent" devices creates at least the presumption -- by way of the doctrine expressio unius est exclusio alterius -- that the FDA does officially approve those products it scrutinizes through the regular Class III PMA process. Such official approval, of course, strongly would imply that federal preemption is present.

[PMA] requirements are preempted," id. - demonstrates that the better reading is that PMA processes are preempted in addition to any other state requirements relating to safety or effectiveness or any other MDA requirement established for the device.[7]

We believe the literal language of the statute compels this result: State requirements pertaining to the safety or effectiveness of a device, or to any other matter included in a requirement made applicable to the device by the MDA, are preempted whenever they are different from, or in addition to, any requirement imposed upon the device under the MDA. Zyderm and Zyplast, it is undisputed, are required by the MDA to undergo the FDA's stringent PMA process. State tort causes of action -- to the extent they relate to safety, effectiveness, or other MDA requirements -- constitute requirements "different from, or in addition to the Class III process; they are, therefore, preempted."[8]

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[7] See Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.), cert. denied, 113 S. Ct. 327 (1992) (finding that MDA Class III devices developed under the FDA "Investigational Device Exemption" ("IDE") regulations are preempted from state tort law liability; although IDE regulations "do not specify the safe and effective design [,] they specify the procedures for determining whether the experimental design is safe and effective" and thus "are requirements relating to safety and effectiveness and they can therefore have preemptive effect"). To our knowledge, Slater and King are the only decisions by federal courts of appeals to have reached the preemptive scope of the MDA's Class III regulations, and both have reached conclusions consistent with our analysis herein. Inasmuch as we have previously determined in Moore that preemption applies in the MDA Class II sphere, extension of that holding to Class III regulations comports with logic and our understanding of the MDA regulatory scheme. Moreover, although we do not need to consult legislative history to decide this issue, we note that Senator Kennedy stated, when he introduced the MDA, that "[t]he most hazardous devices . . . would require full premarket testing and clearance before they are allowed on the market. Premarket clearance represents the highest degree of regulatory control...." 121 Cong. Rec. 10,688 (1975) (emphasis added); see also King, 1993 U.S. App. LEXIS 432, at *22- *28 (Aldrich and Campbell, JJ., concurring) (finding intent of Congress in enacting MDA was to provide maximum of protection available to medical device users).

[8] Nor does the seemingly more restrictive language of § 808.1(d) compel a different result. That section provides that state and local requirements are preempted "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act..." (emphasis added).

C.

Stamps also argues that Collagen's ability to strengthen the contraindications in its packaging and labeling proves that it could *comply with* both state tort law and the federal statute. In essence, Stamps argues that the MDA forms only the floor of regulation; the states are free to construct a regulatory ceiling.

We agree with Stamps that, under the Class III regulatory framework, Collagen could have strengthened its warning labels without first obtaining prior FDA approval. The "Conditions of Approval" issued with respect to Zyderm, for example, provide,

> Changes in labeling, manufacturing, sterilization, packaging, or performance of design specification which enhance safety of the device or safety in the use of the device may be placed into effect by the sponsor prior to the receipt of a written FDA approval of the supplemental PMA....
>
> Specific examples of changes permitted are:
>
> (1) addition of warnings, contraindications, or side effects....

See also 21 C.F.R. § 814.39(d)(2)(i) (permitting without prior FDA approval "[l]abeling changes that add or strengthen a contraindication, warning, precaution or information about an adverse reaction.").

We cannot agree, however, with the conclusion Stamps draws from this -- that the lack of direct conflict between the state and federal regulations compels a finding of no preemption. While we are aware that the court in Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1540-43 (D.C. Cir.), cert. denied, 469 U.S. 1062

Stamps apparently reads out the latter half of this clause and points to the fact that the FDA premarket approval process is not a "specific counterpart regulation" to state tort law. We disagree with this interpretation and need look no further than the second half of the quoted clause. It is plain that § 808.1(d) poses the same test as the statute: When there exists a specific requirement applicable to a particular device under the act -- such as the MDA's PMA requirement for Zyderm and Zyplast -- additional or different state laws are preempted.

(1984), interpreting the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") similar express preemption provision, found no preemption where there was no direct conflict between the state and federal regulation, we do not believe the analysis therein applied can be said to have survived Cipollone, and was directly refuted in Morales. See Morales, 112 S. Ct. at 2038 (rejecting contention that express preemption is inappropriate where state and federal law are consistent).

In Ferebee, the court rejected Chevron's contention that FIFRA's express preemption provision, 7 U.S.C. § 136v(b), which said that states "shall not impose or continue in effect any requirements for labeling...in addition to or different from those required under this subchapter," required a holding of preemption of state tort liability. Instead, the court noted that Congress, although explicitly preempting state labeling "requirements," had not stated its intention to preempt state damages actions. 736 F.2d at 1542. Yet in the statute at issue in Cipollone, Congress had not expressly declared its intent to preempt state damages actions, and the Court nevertheless found them preempted, at least in part. Thus, no such "plain statement" of congressional intent as Ferebee contemplated is required. Moreover, we reiterate our belief that no sound distinction can be drawn between the "no requirement or prohibition" language found dispositive in Cipollone and the express preemption of "any requirement" contained in the FIFRA and the MDA.[9]

---

[9] Lastly, to the extent Ferebee can be read to import a direct conflict requirement into express preemption analysis, it runs afoul of Cipollone, where the Court stated, 112 S. Ct. at 2618, that the language of the express preemption provision alone must guide the preemption inquiry. Direct conflict, moreover, is more appropriately considered as an aspect of implied preemption analysis, particularly of that version that applies where "compliance with both federal and state regulations is a physical impossibility." See Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 142-43 (1963); Osburn v. Anchor Lab., 825 F.2d 908, 912-13 (5th Cir. 1987), cert. denied, 485 U.S. 1009 (1989) (finding no implied preemption in FDA label PMA process for new animal drugs where FDA regulations permitted manufacturer to strengthen label warnings without prior approval).

As Cipollone has clarified, resort to implied preemption analysis is inappropriate where the statute specifies the scope of its intended preemptive effect. Lastly, the MDA is different from FIFRA, although it incorporates a

D.

Finally, we acknowledge that our reading of the MDA effectively denies Stamps access to state law damages actions as a remedy for her injuries. Stamps cites Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984), for the proposition that there is a strong presumption against preemption of state law remedies where no federal remedy exists. Like Stamps's direct conflict argument, however, this too is more appropriately addressed in the context of implied preemption.[10] That is to say, where Congress has expressly preempted state common law damages actions, as in Cipollone and the MDA, its failure to provide a federal remedy will not defeat its intent to preempt state law.[11]

VI.

---

similar express preemption provision. And as regards the preemptive scope of the MDA, the FDA has stated,

> Congress has expressly declared that the Federal Food, Drug & Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption, therefore, does not apply....Under Section [360k(a)] of the act, preemption is not restricted to State requirements that directly conflict with Federal law....

45 Fed. Reg. 67326, 67328 (1980).

[10] See Silkwood, 464 U.S. at 256 (rejecting suggestion that "there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law," but refusing to recognize any such preemption in that case based upon implied "conflict" or "frustration" preemption); Abbott by Abbott v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir.), cert. denied, 488 U.S. 908 (1988) (applying unavailability of federal remedy presumption in impled preemption context).

[11] See Lee v. E.I. DuPont de Nemours & Co., 894 F.2d 755, 757 (5th Cir. 1990) (ERISA's express preemption provision preempts state tort law despite unavailability of federal remedy); see also Slater, 961 F.2d at 1333 ("It would be a mistake to conclude that preemption in these circumstances leaves the consuming public remediless, at least if we have concern for economic substance rather than legal formality and do not suppose that the only 'remedies'. . . are those that the law provides.").

In conclusion, the district court did not err in finding Stamps's state law claims completely preempted by section 360k(a). The summary judgment is AFFIRMED.

IN THE UNITED STATE DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

JENNIFER STAMPS, Plaintiff,	)	[ENTERED OCT 16, 1991]
v.	)	CIVIL ACTION NO. H-90-2242
COLLAGEN CORPORATION Defendant	)	

MEMORANDUM OPINION

This case is before the Court on defendant's motion for summary judgment. Plaintiff alleges in her complaint[1] that she was injected with implants manufactured by defendant, that these implants were defective as manufactured, that defendant failed to provide adequate labeling or other warning of the defects, and that use of the allegedly defective implants caused her injury. Defendant asserts that plaintiff's claims are preempted by the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c, et seq., under which defendant's devices are strictly regulated. Defendant has submitted competent documentary evidence, authenticated by proper affidavit, in support of its motion for summary judgment, the parties have submitted briefs, and the motion is ripe for decision.

Preemption, which is based on the Supremacy Clause of the United States Constitution, "encompasses both federal statutes themselves s and federal regulations that are properly adopted." City of New York v. Federal Communications Comm., 486 U.S. 57 (1988). Absent clear language to the contrary, there is a presumption against preemption in matter regarding health and

---

[1] Plaintiff's first motion for leave to file an amended complaint was subsequently withdrawn by plaintiff. Plaintiff's second motion for leave to file an amended complaint was not filed until after the discovery deadline and has been denied, with certain limited exceptions not relevant to the motion for summary judgment, as untimely.

safety. Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713 (1985).

Section 360k(a) of the MDA expressly provides that no state or political subdivision of a state may establish a safety or effectiveness requirement for a device subject to the provisions of the MDA which is different from or in addition to any requirement applicable under the MDA. The Food and Drug Administration (FDA) has promulgated regulations[2] which define "requirement" to include court decisions. 21 C.F.R. § 808.1(b). The FDA regulations also establish that state requirements are preempted where 'the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . ." 21 C.F.R. § 808.1(d).

It is undisputed that the devices used by plaintiff are subject to the MDA. The devices were classified by the FDA as Class III medical devices and, as a result, required FDA "premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). Pursuant to 21 U.S.C. § 360e(c), defendant was required to provide comprehensive information to the FDA, including information regarding design, manufacturing methods, proposed packaging and labeling, and data from premarketing laboratory tests and clinical investigations. Following extensive review, the FDA issued an approval order for the devices and the proposed labeling and thereby authorized the devices for marketing in strict compliance with the approval. Under federal law, approved Class III devices may not be manufactured, packaged or labeled in a manner different from the approval order. 21 C.F.R. § 814.80. Plaintiff's evidence that the FDA seized certain Collagen products which omitted language recently required for the new package inserts is a clear indication of the applicability of the regulations and the strength with which they are enforced by the agency.

The United States Court of Appeals for the Fifth Circuit, citing the FDA regulations discussed above, has held that state law claims are preempted where the FDA "has established specific counterpart regulations or there are other specific requirements

---

[2] Plaintiff has neither asserted not [sic] presented evidence that the FDA regulations discussed herein were not properly adopted.

applicable to a particular device under the act. . ." Moore v. Kimberly-Clark Corp., 867 F.2d 243, 245 (5th Cir. 1989), quoting 21 C.F.R. § 801.1(d). Plaintiff attempts to avoid summary judgment by noting that defendant has not identified "specific counterpart regulations" governing the devices at issue. The regulation and the Moore case, however, require either specific counterpart regulations or other specific requirements applicable to a particular device. In this case it is clear that the FDA has established specific requirements applicable to the Collagen devices. The detailed requirements are set forth in the approval order and cannot be varied without FDA consent. Nor can the requirements be varied by state law or court decision. 21 U.S.C. § 360k(a). See also Moore, 867 F.2d at 244.

The Court recognizes that in Moore the device at issue had been classified by the FDA as a Class II medical device. The FDA regulates labeling of Class II devices, but does not have regulations dealing with their construction or design and does not require premarket approval. As a result, the Fifth Circuit held that plaintiff's warning and labeling claims were preempted, while her claims for defective construction and design were not. In the case at bar, however, the subject implants are Class III medical devices which require premarket approval as to manufacturing methods, labeling, packaging, etc. Consequently, the preemptive effect of the MDA would also reach plaintiff's claim for defective manufacture and design. See Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653, 656 (D.S.C. 1988).

Because the implants at issue in this case are subject to specific requirements under the MDA regarding manufacture, packaging and labeling, plaintiff's claims regarding defective manufacture, labeling and warning are preempted. As a result, defendant's motion for summary judgment must be granted. An appropriate final judgment and order consistent with this memorandum opinion shall be signed this day.

SIGNED this 11th day of October, 1991.

/s/ James DeAnda
Chief Judge
United States District Court

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 92-2084

JENNIFER STAMPS,

Plaintiff-Appellant,

VERSUS

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Southern District of Texas

ON PETITION FOR REHEARING

(MARCH 19, 1993)

Before GOLDBERG, SMITH, and EMILIO M. GARZA, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in above entitled and numbered case be and the same is hereby DENIED.

ENTERED FOR THE COURT:

/s/ Jerry E. Smith
United States Circuit Judge

Supreme Court, U.S.
FILED
AUG 16 1993
OFFICE OF THE CLERK

(2)

No. 92-1989

IN THE
Supreme Court of the United States
OCTOBER TERM, 1993

JENNIFER STAMPS,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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MEMORANDUM FOR THE RESPONDENT IN OPPOSITION

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August 1993

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Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

MEMORANDUM FOR THE RESPONDENT IN OPPOSITION

This case presents the same question as the petition in *King v. Collagen Corp.*, No. 92-1979, namely, whether state tort actions against medical device manufacturers are expressly preempted under federal law when they seek the imposition of labeling or design requirements that differ from corresponding federal requirements.[1] The courts of appeals in this case and in No. 92-1979 held that tort actions are expressly preempted in these circumstances. The petitioner in this case, represented by

[1] Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries (except wholly owned subsidiaries) of respondent Collagen Corporation: Target Therapeutics, Inc., Coll-Optics, Inc., Prograft Medical, Inc., and LipoMatrix, Inc.

the same counsel as the petitioner in No. 92-1979, has filed a protective petition, seeking only that it be disposed of consistently with the Court's disposition of the petition in No. 92-1979 (Pet. 5).

Respondent likewise submits that this petition should be denied for the same reasons as those stated in its brief in opposition in No. 92-1979.

Respectfully submitted,

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August 1993

Supreme Court, U.S.
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Brief of Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as Amici Curiae in Support of Petitioners

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Pursuant to Rule 37 of the Rules of this Court, Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as amici curiae, respectfully submit this brief in support of the petitions for writ of certiorari submitted by Jane King in No. 92-1979 and Jennifer Stamps in No. 92-1989.[1]

---

[1]Amici have submitted, under separate cover, identical briefs on both petitions, and refer in both briefs to the decisions of both the First and Fifth Circuit Courts of Appeals and to both the King and Stamps petitions.

Statement of Interest

The Courts of Appeals for the First and Fifth Circuits have decided that the States may not provide their citizens with tort law remedies for injuries caused by dangerous medical devices.

These decisions nullify the States' historic reliance upon tort law as the principal protection for their citizens from unsafe conduct and conditions. State tort law both compensates injured individuals, paying their medical and other expenses, and provides a powerful incentive to those who engage in potentially dangerous activities to minimize the risks of those activities. Through long processes of court decision and legislative action, the States have developed and refined their tort systems to balance the needs and rights of victims against the needs and rights of manufacturers of potentially dangerous products, such as the product that caused the injuries in these cases.

Where, as here, the States have exercised their basic powers to protect the health and welfare of their citizens, the federal courts must presume that there is no preemption of state action unless preemption is the "clear and manifest" intent of Congress. *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

The States submit this brief in order to assist this Court in reviewing the petitions, and to urge this Court, in light of this presumption against preemption and the specific circumstances of this case, to restore to the States the ability to provide tort remedies to their citizens who have been injured by dangerous medical devices.

Summary of Argument

The Courts of Appeals have decided that the safety measures employed by private manufacturers of medical devices are, when approved by the FDA, and in some cases, even when they are not approved by FDA, federal requirements that preempt state law. Their decisions go far beyond this Court's decisions in this area, which have only found preemption of state safety-related law where the federal government itself has enacted a safety standard.

The decisions of the Courts of Appeals deprive persons injured by the most dangerous class of devices of their state tort law remedies for those injuries. The impact of this decision will be profound. Not only will persons injured by dangerous devices have no legal remedy for their injuries, but the amount of safety that users of all medical devices can expect will be severely diminished. The FDA's premarket approval process is inadequate to ensure device safety, both because it is an imperfect process based upon incomplete information, particularly about long term and less common safety hazards, and because the removal of possible state tort law liability creates incentives for manufacturers to be less than candid with the FDA about known safety hazards.

The decisions of the Courts of Appeals are based upon the mistaken belief that Congress, as a matter of policy, intended premarket approval to be the maximum protection provided to the public. The plain language of the statute itself undermines this misconception by providing for more stringent regulation by the states.

In reaching their decision, the Courts of Appeals ignored this Court's admonitions to interpret express preemption provisions of statutes primarily in light of the language of the statute itself. The plain language of the statute indicates that only state laws specifically relating to a particular medical device are preempted, and that state laws of general applicability, such as the common law of torts, are not.

This plain language interpretation is consistent with the interpretation of the statute adopted by the FDA when it promulgated its preemption regulations and with the interpretation of the only state supreme court to have considered the issue. The interpretations of the Courts of Appeals conflict with both the FDA's and the state supreme court's interpretations.

Finally, the Courts of Appeals decided that all of the petitioners' state law causes of action are preempted, including their breach of warranty and fraud claims. However, the statute at issue here is very similar to the statute at issue in *Cipollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 2618 (1992), which this Court held did not preempt causes of action based upon breach of warranty or fraud.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Argument

I. This Court should determine that federal approval of a manufacturer's medical device specifications does not preempt state tort law causes of action.

The Courts of Appeals have interpreted the Food, Drug, and Cosmetic Act as stripping away essentially all legal remedies for persons who are injured by class III medical devices, the most dangerous class of medical devices.[2] In place of those remedies, they have installed the Food and Drug Administration's ("FDA") premarket approval procedures as the sole source of public protection from these devices.

This interpretation of the medical device provisions of the Food, Drug and Cosmetic Act, which have not yet been considered by this Court, greatly impacts the health and well being of medical device consumers. It will not only prevent the petitioners here from obtaining redress for their injuries, but will prevent all persons who are injured by dangerous medical devices from being compensated for their injuries. Moreover, the Courts of Appeals' reliance upon premarket approval procedures to protect the public health is fundamentally misplaced, as those procedures alone are inadequate to ensure that class III medical devices are safe.

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[2] 21 U.S.C. §360c(a)(1) establishes 3 classifications for medical devices: Class I, Class II, and Class III. Briefly, class I devices are devices for which the general provisions of the Act regarding misbranding, adulteration, good manufacturing practice and other matters are sufficient to provide reasonable assurance of safety and efficacy. Examples of class I devices include ice bags, tongue depressors, examination gloves, and crutches.

Class II devices are devices for which the general controls applicable to class I devices are insufficient to provide a reasonable assurance of safety and effectiveness, and for which there is enough information about the device to establish a special performance standard to provide that assurance. Examples of class II devices include: clinical electronic thermometers, intravascular catheters, and piston syringes.

Class III are devices which present too great a risk to be class I devices and for which insufficient information exists to establish a class II performance standard. Examples of class III devices include: replacement heart valves, intaocular lenses (for implantation into the eye), and contraceptive intrauterine devices (IUDs).

The impact of the Court of Appeals' decisions on the lives of persons who use medical devices is tremendous. This Court should consider and definitively determine the scope of preemption in the medical device area.

a. Federal approval of a manufacturer's medical device specifications is not a federal requirement that triggers preemption of state law.

This Court has not considered whether the kind of federal activity at issue here gives rise to preemption. The Courts of Appeals, without much analysis, held that FDA approval of a manufacturer's premarket application is a federal "requirement" which triggers preemption of state law. In fact, the role of the FDA in this area is substantially different from the federal role in other cases where this Court has found federal safety related activity to preempt state law. For example, in both *Cipollone* and *CSX Transportation, Inc. v. Easterwood*, 113 S.Ct. 1732 (1993), this Court's most recent pronouncements concerning federal health and safety requirements and state tort law, this Court found preemption where the federal government promulgated a safety standard with which compliance was mandatory. In *Cipollone*, Congress required specific warning statements to be included in cigarette advertising. In *CSX Transportation*, the Federal Railroad Administration set specific speed limits that were to be observed by railroad operators. In both cases, preemption was triggered by a specific standard promulgated by the federal government.

By contrast, the FDA's role with respect to an application for premarket approval is to merely determine, as a matter of fact, whether the application meets the statutory criteria for approval. If the application meets the criteria, then it must be approved. 21 U.S.C. § 360e(d). The specifications for the design, manufacture, and labeling of the device are set forth by the manufacturer in the application and they are solely the manufacturer's responsibility. 21 U.S.C. § 360e(c).

A manufacturer has broad discretion in how it structures its device specifications to meet the criteria for approval. If a device presents a particular safety hazard, a manufacturer, depending upon the nature of the hazard, may choose from a variety of options in minimizing the hazard. The manufacturer may redesign the device to eliminate the hazard, include a warning in the labeling of the device so that users may avoid the hazard, limit the indications for use of the device so it is not used in a manner that gives rise to the hazard, or take some combination of those actions. As long as the option chosen by the manufacturer supports a finding by the FDA that there is a "reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling" of the device, then the FDA must approve the manufacturer's application. 21 U.S.C. § 360e(d)(1)(A).

Once a manufacturer has obtained FDA approval, it is free to make substantial safety related modifications to the device without first submitting those modifications to the FDA for review. 21 C.F.R. § 814.39(d) permits the following changes to be made without prior approval of the FDA:

> i. Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction.
>
> ii. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.
>
> iii. Labeling changes that delete misleading, false, or unsupported indications.
>
> iv. Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

By virtue of the nature of the premarket approval process and these regulations concerning post-approval modifications, device manufacturers have great latitude within which they can establish and modify their own substantive safety

specifications. By contrast, the cigarette manufacturers subject to federal warning requirements and the railroad operators subject to federal railway speed limits have no such discretion. For them, the federal government has established a substantive standard, from which they may not vary.

The device manufacturer's safety-related undertakings do not resemble federal safety standards so much as they resemble the undertakings of a warrantor who determines what characteristics a product will have and promises that the product will live up to those characteristics. In *Cipollone*, this Court held that an express warranty, because it was an undertaking of the manufacturer, was not a government requirement. *Cipollone*. at 2622. The same rationale should apply in this case. Because of the freedom accorded to manufacturers to pick and choose the safety measures they will include in their applications for premarket approval, those measures should not be treated as federal safety requirements that preempt state law.

b. The federal medical device approval process does not adequately protect the public health and should not serve as the public's sole protection from dangerous medical devices.

The devices which must be submitted for premarket approval, class III devices, must be so submitted because they present a potentially unreasonable risk of illness or injury and because their workings and effects on the human body are not well understood. 21 U.S.C. § 360c(a)(1)(C). Class III devices have not been generally used in medical practice, and there is no wide body of experience from which judgments of safety can be made. By definition, there is not enough information concerning these devices for the FDA to be able to promulgate a class II performance standard that would give a reasonable assurance of safety. 21 U.S.C. § 360c(a)(1)(C)(i)(II).[3] As result, the

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[3]It is useful to contrast the devices at issue here to the federal railroad speed limits at issue in *CSX Transportation*, and the federal health warnings at issue in *Cipollone*. With over one hundred years of experience with railroad transportation, it may fairly be said that railroad speed limits may be

FDA must act on an application for approval of a class III device without complete information about the safety of the device. In particular, it is most often without information about long term and less common side effects.

Typically, the FDA relies upon clinical studies, in animals and humans, to attempt to judge the safety of a proposed device. *See* 21 C.F.R. § 814.20 (required contents of application, with extensive discussion of requirements for clinical studies). Unfortunately, no clinical study can reliably identify all of the possible side effects, particularly the long range side effects, of a new device. Such studies are generally conducted only for a relatively short term and with a relatively small number of subjects. While they are useful in determining the gross effects of a device on the human body, they are not as reliable in detecting less common effects or effects which only manifest themselves over the long term. The FDA itself recognizes the inherent difficulties in relying upon clinical studies to determine the safety of devices, and as a result, almost always requires post-approval monitoring of problems that arise in connection with the actual use of devices in the marketplace. Because of the limitations on the information available for the kinds of devices that must go through the premarket approval process, it is not surprising that once a device is approved and marketed widely, significant safety hazards may be discovered.

The case at bar graphically illustrates the problems that can arise when a device is approved without complete information concerning the safety hazards it presents. Zyderm was approved for use by the FDA in 1981. However, it was not

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determined with a reasonable degree of confidence that the limits will ensure safety. Similarly, federal cigarette warnings were not promulgated until after years of scientific and public debate about the effects of smoking on health. By contrast when the FDA receives an application for approval of a brand new medical device, the hazards of the device are not entirely known, and the appropriate measures to minimize those hazards are also not well understood. In that environment, it is difficult to be confident that the approval process will ensure a desired level of safety. This Court should hesitate before ascribing to the premarket approval procedure the power to prevent future injuries to such an extent that it is no longer necessary to provide for a system of compensation for those injuries which do occur.

until several years later that a link between Zyderm and the disorder at issue here, dermatomyositis or polymyositis ("DM/PM"), was suspected. The linkage between DM/PM and Zyderm was primarily established by post-approval epidemiological evidence, which by its very nature can only be examined after a device has been widely used. In fact, the first published, peer reviewed study concerning this link did not appear until June of 1993, 12 years after Zyderm was initially approved by the FDA.[4] Because the information connecting DM/PM and Zyderm was unavailable to the FDA at the time of Zyderm's approval, the approval process provided no protection at all for the victims of this disorder.

Even if the FDA were able to know about all of the possible hazards presented by a device at the time the device is presented for approval, the premarket approval process has other shortcomings that render it inadequate as the sole source of public protection against dangerous devices.

The FDA cannot, as part of the premarket approval process, determine that a manufacturer will not negligently or intentionally alter the design, manufacture or labeling of a device in some way that might create a safety hazard. The FDA cannot ensure that a manufacturer will not negligently or intentionally make false or misleading statements about a device in advertising. Nothing in the premarket approval process provides any assurance that a manufacturer will conduct itself without negligence or other tortious conduct after its device has been approved. Indeed, given these facts and the freedom granted to manufacturers to make safety related changes to their devices after they have been approved, users of medical devices can never really be assured that the device they are using is the same as the device that was reviewed by the FDA.

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[4]Cukier, Beauchamp, Spindler, Spindler, Lorenzo, and Trentham, *Association between Bovine Collagen Dermal Implants and a Dermatomytosis or a Polymyositis-like Syndrome*, 118 Annals of Internal Medicine, June 15, 1993, at 921.

Because of the inherent difficulties in attempting to determine all of the risks posed by a particular device and the problems associated with monitoring manufacturer conduct after the device has been approved, FDA approval of the device provides only a minimum assurance of safety.[5] The Courts of Appeals have elevated this minimum assurance to the maximum assurance of safety that the public can have. This Court should intervene to preserve the measures that the States have taken to provide their citizens with additional protection.

c. State tort law is the only source of compensation for persons injured by dangerous medical devices and provides incentives for manufacturers to ensure safety both during the federal approval process and afterward.

The incentives provided by the state tort system make the premarket approval process work. The potential of tort liability for a serious safety defect provides an incentive for manufacturers to test their products thoroughly and to provide complete data to the FDA. It similarly motivates them to engage in rigorous post-marketing surveillance so that they will be alerted to any undiscovered safety hazards in as timely a manner as possible. These incentives are important, because without them, the regulatory scheme creates perverse incentives to suppress information about safety hazards.

In the environment created by the Courts of Appeals, a manufacturer of a Class III device need only look to the FDA for permission to market its device. As long as the FDA has approved the device and that approval is not withdrawn, the manufacturer may profitably market the device. That source of profit is jeopardized by any negative safety information that

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[5]This is not to say that FDA approval is useless. It serves as a vitally important screening point to eliminate the thousands of blatantly fraudulent, inadequately tested and quack devices that would flood the marketplace were FDA approval not a prerequisite for marketing all but the most innocuous (class I) or well understood (class II) devices. The point of this discussion is that as the sole source of public protection from class III devices, FDA approval is inadequate.

might cause the FDA to disapprove an application for premarket approval or to withdraw a previously granted application. While certainly most reputable manufacturers would still act upon negative safety information, there would be no sanction for manufacturers who either negligently or intentionally fail to do so. In such cases, the FDA's premarket review process would become a bureaucratic shell game with little real protective value.

In addition, as discussed above, there are situations in which a manufacturer can make significant safety related changes to an approved device or its labeling without seeking additional prior approval from the FDA. While the regulation permitting these changes is intended to permit manufacturers to immediately act upon safety problems that slip past premarket review or that are discovered after approval is given, they provide no protection for the public if manufacturers make these changes, either negligently or intentionally, in ways that cause additional injuries to consumers of devices. Only state tort laws impose duties with respect to these product changes.

Finally, and most importantly, the tort law system is the only mechanism by which persons injured by devices can be compensated for their injuries. Even where the federal government has taken over exclusive responsibility for ensuring safety in a particular industry, as is the case in the civilian nuclear power industry, this Court has been reluctant to deprive individual citizens of tort remedies for injuries resulting from that industry's activity. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

The Courts of Appeals have determined that manufacturers of Class III devices should be free of state tort liability. In so doing the Courts of Appeals have created a regulatory climate in which persons injured by dangerous medical devices have no legal remedy for their injuries and in which the sole protection for users of such devices is an imperfect FDA review process, which is itself undermined by the perverse incentives created by the elimination of tort

liability. In so doing, the Courts of Appeals have strayed beyond the reach of *Cipollone* and *CSX Transportation*. They have extended federal preemption of state safety law to areas where the federal government has not enacted its own safety standards, but has merely approved the safety standards of private manufacturers. Because this case raises both important safety issues and an unsettled extension of federal preemption law, this Court should grant the petitioner's request for review.

II. This Court should review the decisions below because they are inconsistent with this Court's Supremacy Clause jurisprudence and create judicial and administrative agency conflicts that only this Court can resolve.

a. The Courts of Appeals based their decisions on presumptions which conflict with the plain language of the express preemption provision here, in contravention of this Court's admonitions that express preemption provisions be interpreted by their own terms.

The touchstone for determining Congressional intent to preempt must be the language of the statute claimed to have preemptive effect, particularly when that statute contains an express preemption provision. *CSX Transportation, Inc.*, at 1737, *Cipollone*, at 2618.

However, instead of following to their logical and natural conclusion the basic principles of statutory construction employed by this Court, the Courts of Appeals, particularly the First Circuit, constructed their own views of congressional intent upon which they based their own erroneous interpretations of the statute.

The First Circuit, relying upon legislative history which had nothing to do with the preemption provision at issue, determined that the Congressional purpose was to establish FDA requirements as the maximum protection to be afforded the individual user. *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir. 1993). The court then concluded that the statutory language conformed to its view of congressional intent. *Id.*

The First Circuit's approach not only ignores this Court's established principles of statutory interpretation, the policy prescription upon which it is based is at odds with the language of the statute.

The savings clause in 21 U.S.C. § 360k(b) provides that the FDA may exempt state requirements from preemption if the state requirement "is more stringent than a requirement under this Act...." It is highly unlikely that Congress intended subsection (a) of 21 U.S.C. § 360k to establish the FDA's requirements for devices as the maximum level of public protection when in subsection (b) of the same provision it authorized states to enact and maintain more stringent requirements for devices. Clearly, as both Stamps and King argued to the Courts of Appeals, FDA requirements are minimum requirements which can be augmented by state requirements. The interpretations of the statute by the Courts of Appeals should not have been biased by the misconception that Congress intended premarket approval to be the maximum protection afforded the public.

Stripped of the policy bias adopted by the Courts of Appeals, the most natural reading of the statute here preempts only state requirements that are targeted at a specific device, such as hearing aid regulations, rather than requirements of general applicability, such as the common law of torts. This conclusion flows from the specific words used in the device preemption provision of the Food, Drug and Cosmetic Act. That provision provides:

> [N]o State...may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device....

21 U.S.C. § 360k(a).

Webster's New Collegiate Dictionary defines "respect" as "a relation to or concern with something usually specified" and defines "respecting" as "in view of" and "with regard to."

WEBSTER'S NEW COLLEGIATE DICTIONARY 986 (1977). The common law of torts does not have any specified relationship with "a device," nor was it developed in view of or with regard to "a device." Therefore, if the phrase "with respect to a device" is to be given its plain dictionary meaning, the common law is not a "requirement with respect to a device."

In reaching a contrary interpretation of the scope of preemption, the Courts of Appeals ignored the difference between the phrase "with respect to," used by Congress to describe the state requirements preempted, and the word "applicable," used by Congress to describe the federal requirements that trigger preemption. Webster's defines "applicable" as "capable of or suitable for being applied," and supplies the following example: "There are several statutes applicable to the case." *Id.* at 54. The interpretation of the Courts of Appeals is supportable if one substitutes the phrase "applicable to" for the phrase "with respect to" in the statute. Certainly, the common law of torts is applicable to devices. If Congress had intended to include state requirements that are merely applicable to a device, then it could have used "applicable to" in place of "with respect to," as it did in the clause of the provision describing the federal requirements triggering preemption. Congress's choice to use a narrower phrase to describe the state laws within the scope of preemption than the phrase it used to describe the federal laws triggering preemption should be given effect.

That Congress did not intend preemption of general state laws that have no reference to a medical device is further reinforced by the use of the word "device" in the singular. Had Congress intended to preempt generally applicable state laws, it would more likely have used the phrase "with respect to devices" rather than "with respect to a device." Moreover, the phrase "federal requirement applicable under this chapter to the device" uses the word "the device" to refer back to the device referenced by the preempted state requirement. This reference back to the specific device regulated by state law

makes no sense when applied to the general common law, as the common law makes no reference to any medical device.

In their rush to validate their own policy presumptions, the Courts of Appeals failed to adequately consider the import of the preemption language used by Congress. As evidenced by that language, Congress did not intend to preempt common law tort causes of action.

b. The decisions of the Courts of Appeals conflict with the FDA's preemption regulations and with a recent decision of the Supreme Court of Hawaii.

The decisions of the Courts of Appeals are, as discussed at length in the King Petition at 13-15, inconsistent with the FDA's regulation implementing 21 U.S.C. §360k and with the decision of the Supreme Court of Hawaii in *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Hawaii 1992).

The FDA has determined, as is argued herein, that only state requirements specifically directed at devices are preempted. In adopting its regulations implementing the preemption provision of the statute, it determined that "State or local requirements of general applicability where the purpose of the requirement relates...to other products in addition to devices..." are not preempted. 21 C.F.R. § 808.1(d).

In *Larsen* the Supreme Court of Hawaii determined that premarket approval is not a federal requirement that triggers preemption under the statute. The court reviewed the federal regulations concerning premarket approval and concluded that they merely set forth general procedural requirements which did not trigger preemption analysis under the statute.[6] *Larsen*, at 1282.

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[6] The *Larsen* case, like this case, provides another example of a safety hazard discovered after FDA approval. *Larsen* involved an approved pacemaker that was recalled after it was discovered that it malfunctioned at temperatures slightly above normal body temperature. The plaintiff in Larsen endured several surgeries, including major open heart surgery, and life threatening complications in order to replace his FDA approved pacemaker.

The interpretations of the FDA and the Supreme Court of Hawaii conflict with the interpretations of the Courts of Appeals. This conflict can only be resolved by this Court.

c. The Courts of Appeals analyzed the breach of warranty and fraud claims in these cases in contravention of the principles set forth in this Court's *Cipollone* decision.

Even if this Court were to determine that Congress intended to preempt common law causes of action in this area, the conclusion of the Courts of Appeals that common law actions for fraud, misrepresentation, and breach of warranty are preempted directly conflicts with this Court's holding in *Cipollone*.

The preemption provision at issue in *Cipollone* and the provision at issue here are similar in that both statutes preempt state "requirements." In *Cipollone*, this Court held that the requirements upon which a breach of warranty claim is based are imposed by the manufacturer, not the state, and therefore are not state "requirements." *Cipollone*, at 2633. There is no basis for distinguishing this case. The requirements upon which the breach of warranty claims here are based are imposed by Collagen upon itself, not by the states, and therefore are not preempted state "requirements."

Stamps' and King's fraud and misrepresentation claims should also be found not to be preempted. In *Cipollone*, this Court distinguished between requirements arising out of a duty not to deceive, and requirements arising out of a duty to make such warnings as are necessary to make a product reasonably safe. *Cipollone*, at 2624. The Court held that only the latter class of requirements were preempted because they related to "smoking and health." The Court held that because fraud and misrepresentation claims arose out of a duty not to deceive rather than a duty relating to smoking and health, fraud and misrepresentation claims were not preempted. *Id.*

In this case, only requirements relating to the "safety and efficacy" of a device are preempted. 21 U.S.C. § 360k(a). This

language is essentially the same as that in the Public Health Cigarette Smoking Act, and should be similarly construed to preempt only requirements arising out of a duty to warn of unreasonable safety hazards. Requirements arising out of a generalized duty to be truthful should not be preempted.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Conclusion

For the foregoing reasons, the Petitions for Writ of Certiorari should be granted.

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August 16, 1993

No. 92-1989

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

JENNIFER STAMPS,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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MEMORANDUM FOR THE RESPONDENT IN OPPOSITION

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MEMORANDUM FOR THE RESPONDENT IN OPPOSITION

This case presents the same question as the petition in *King v. Collagen Corp.*, No. 92-1979, namely, whether state tort actions against medical device manufacturers are expressly preempted under federal law when they seek the imposition of labeling or design requirements that differ from corresponding federal requirements.[1] The courts of appeals in this case and in No. 92-1979 held that tort actions are expressly preempted in these circumstances. The petitioner in this case, represented by

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[1] Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries (except wholly owned subsidiaries) of respondent Collagen Corporation: Target Therapeutics, Inc., Coll-Optics, Inc., Prograft Medical, Inc., and LipoMatrix, Inc.

the same counsel as the petitioner in No. 92-1979, has filed a protective petition, seeking only that it be disposed of consistently with the Court's disposition of the petition in No. 92-1979 (Pet. 5).

Respondent likewise submits that this petition should be denied for the same reasons as those stated in its brief in opposition in No. 92-1979.

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